E1 cont
W7 cont

transmitting the third amount of light reflected from the surface of the test strip through a second fiberoptic bundle to the photodetector.

REMARKS

Any fees that may be due in connection with this response may be charged to Deposit Account 50-1213. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Attention is directed to the patent of Khoja et al., U.S. Patent No. 5,665,310, which was cited in the Information Disclosure Statement mailed March 7, 2001.

Claims 1, 3-9 and 11-30 are pending in this application. Claim 2 is cancelled and incorporated into claim 1. Claims 1, 5, 9, 11, 12, 17, 18, 20, 21, 29 and 30 are amended herein. The claims are amended to place claims in independent form or to correct minor language inconsistencies, and in order to more particularly point out and distinctly claim the subject matter. No new matter has been added nor are the amendments intended to alter the scope of the claims or to avoid any cited art.

Claim 1 is amended by incorporation of claim 2, which was are objected to as being dependent upon a rejected base claim and allowable if rewritten as an independent claim. Accordingly, claim 1 and all claims dependent thereon (claims 3, 4, 8-13, 15-17 and 22-28) should be allowable. Only claims 5-7, 14, 17, 18, 20, 29 and 30 remain rejected.

Pursuant to 37 C.F.R. § 1.121, included as an attachment is a marked-up version of the claims that are amended.

FINALITY OF THE OFFICE ACTION

It is respectfully submitted that the Office Action mailed November 26, 2002, (hereinafter the Office Action), which was made Final, introduces new grounds of rejection of claims 1, 3-4 and 8-9 under 35 U.S.C. §103 and a rejection under 35 U.S.C. §112, second paragraph, that were not necessitated

by amendment and that could have been applied in a previous Office Action. Therefore, the Action should not have been made Final.

1. Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite in the recitation of "substantially optimally." This language was present in claim 12 as originally filed; claim 12 was not previously rejected on this basis. This basis for removal of finality is not discussed in the Petition; it however is a cogent reason, and a clear introduction of a new ground of rejection not necessitated by amendment.

2. As discussed in the Petition, in the previous Office Action dated May 22, 2002, (hereinafter the previous Office Action), claims 1, 3-4 and 8-9 were rejected under 35 U.S.C. §102 as anticipated by Connolly (WO96/13707).

Prior to amendment, claim 1 recited:

1. (Amended) A method for reading the surface of a test strip comprising an image, comprising:
scanning a reader head in a reflectance reader of to a first position over the surface comprising the image;
determining a first amount of light reflected from the surface comprising the image;
illuminating the surface with light of a first wavelength, and determining a second amount of light reflected from the surface;
illuminating the surface with light of a second wavelength, and determining a third amount of light reflected from the surface; and
determining a parameter correlated with the intensity or shape of the image.

Amended claim 1 reads as follows:

1. (Amended Twice) A method for reading [the] a surface of a test strip comprising an image, comprising:
[scanning] moving a reader head in a [reflectance] reflectance reader [of] to a first position over the surface comprising the image;
[determining] measuring a first amount of light reflected from the surface comprising the image;
uniformly illuminating the surface with light of a first wavelength, and [determining] measuring a second amount of light reflected from the surface; and

uniformly illuminating the surface with light of a second wavelength, and [determining] measuring a third amount of light reflected from the surface[; and

determining a parameter correlated with the intensity or shape of the image].

It is clear that the meaning of "scanning" is the same as the meaning of "moving." For example, at page 46, lines 8-13, of the specification states:

> the reader head **706** is moved (scanned) across the bar code and/or test strip.

Another example is found in the specification at page 47, lines 15-18, which states:

> [t]he control circuit moves (scans) the head across the exposed surface of the bar code or test strip.

Thus, in accordance with teachings in the specification (as well as the ordinary meaning of words), the terms "scan" and "move" have similar meanings of changing the position of the reader head with respect to the surface of the test strip. Accordingly, amendment of claim 1 by substituting "moving" for "scanning," does not add an element. The element was present in claim 1 prior to amendment. The original claim included the requirement that the reader head change position with respect to the surface of the test strip and is the basis upon which the claims were distinguished from the cited reference Connolly in the previous response. Thus, the claims prior to amendment included a step of "scanning a reader head ... over the surface" of a test strip. (Claim 1, lines 3-4). In arguing the impropriety of the rejection, it was noted that Connolly cited in the previous Office Action does not anticipate the claims because it fails to disclose a method with a step of scanning a reader head over the surface of a test strip.

In the Final Office Action, claims 1, 3-4 and 8-9 are rejected under 35 U.S.C. §103 as being unpatentable over Connolly (WO96/13707) and Augstein (U.S. Patent 5,665,310) because Augstein allegedly teaches a reader head that can scan over a the surface of a test strip. Thus, the new ground for rejection is directed to an element already present in the claims prior to amendment.

Accordingly, the new ground of rejection could have been applied in the previous Office Action and is not necessitated by amendment to the claims.

The Office Action indicates that the amendments to the claims necessitated the new grounds for rejection. The amendment to the claims, did not add the requirement that the reader head scan over the surface of the test strip. The amendment to claim 1, set forth above, changes the term "scanning" to the similar term "moving" in order to more distinctly indicate that the reader head changes position with respect to the surface of the test strip and was made in response to the various rejections under 35 U.S.C. 112, second paragraph. Therefore, the new ground is not necessitated by the amendment of claim 1, since the element of changing the position of a reader head (i.e., "scanning" or "moving") was present in the claims as pending prior to the amendment.

Failure to withdraw the finality of the Office Action denies the Applicant the right to address the rejection, which could have been set forth in the previous non-final Office Action. Therefore, it is respectfully submitted that since the newly recited rejections of claims 1, 3-4 and 8-9 under 35 U.S.C. §103 as well as the rejection under 35 U.S.C. §112, second paragraph, are not necessitated by amendment and could have been raised in the previous Office Action, the finality of the Office Action is improper.

THE REJECTIONS OF CLAIM 12 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. The Office Action states that the term "substantially optimally" is indefinite. Claim 12 is amended herein to delete the term "substantially optimally." Accordingly, reconsideration of the ground for this rejection is respectfully requested in view of the amendment to claim 12 herein.

THE REJECTIONS OF CLAIMS 1, 3-9 and 11-30 UNDER 35 U.S.C. §103

Relevant law

To establish a *prima facie* case of obviousness, prior art references when combined must teach or suggest all the claim limitations. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Another requirement to establish a *prima facie* case of obviousness is a teaching or suggestion to modify or combine the references to arrive at the claimed invention. "Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." *In re Fritch*, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (emphasis original). "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, at 1783-84. Without the teachings of the prior art suggesting the combination, it is impermissible to pick and choose among isolated disclosures in the prior art to conclude that the claimed invention is obvious. *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

THE REJECTION OF CLAIMS 1, 3-4, 8-9, 16-18 AND 21-28 UNDER 35 U.S.C. §103(a)

Claims 1, 3-4, 8-9, 16-18 and 21-28 are rejected under as being unpatentable over Connolly (International PCT application No. WO96/13707) in view of Augstein (U.S. Patent No. 5,665,310) because it allegedly would have been obvious to modify the reader head of Connolly, which has one or more light sources, with the teachings of Augstein regarding a moving reader head. This rejected is respectfully traversed. It is respectfully submitted that this rejection is inapplicable to claims 1, 3, 4, 8, 9, 11-13, 15, 16 and 22-28. Claim is amended to incorporate claim 2, which is objected to as being dependent upon a rejected base claim and would be allowable if rewritten as an independent claim or as dependent upon an allowable base claim. Claim 1 as

amended is claim 2 rewritten as an independent claim. Accordingly, only claims 17, 18 and 21 remain rejected on these grounds.

The claims

Previously pending claim 1 was directed a method for reading the surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface having the image, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, and uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface.

Claim 17, which has been rewritten as an independent claim incorporating all limitations of claim 1 as previously pending, is directed to the method of claim 1, further including moving the reader head to a second position over the surface comprising the image; measuring a fourth amount of light reflected from the second position on the surface comprising the image; uniformly illuminating the second position on the surface with light of the first wavelength, and measuring a fifth amount of light reflected from the surface; uniformly illuminating the second position on the surface with light of the second wavelength, and measuring a sixth amount of light reflected from the surface; and determining a parameter correlated with an intensity or shape of the image.

Claim 18, which has been rewritten as an independent claim incorporating all limitations of claim 1 as previously pending, is directed to the method of claim 1, further including repeating the measuring and illuminating steps at additional positions on the surface of the test strip and determining an intensity or shape of the image.

Claim 21 has been similarly amended, and is directed to the method of claim 1, further including moving the reader head to a plurality of positions and

making light measurements at each of the positions to determine an intensity or shape of the image.

Connolly

Connolly teaches a diagnostic test strip for use in an analyzer for measuring analyte in a sample. The test strip includes an elongated body having first and second ends and a hinged portion between the ends so that the first end is foldable over the second end or the body. The first and second ends each have an opening aligned with each other when the first end is folded. A carrier layer means includes a separating layer for whole blood cells.

In methods that use the test strip, the density of a color reaction is determined using a spectrophotometric device that includes a hand-held housing, a test strip holding region that is located above three light detectors or sensors each disposed within a port. During test operation, a test strip is inserted into the holding region so that the test strip openings are located adjacent to the ports. Multiple wavelengths can be used to irradiate the strip in conjunction with multiple chromophores, or with different angles of emission when the light emitters are at different angles with the surface of the test strip.

Light sensors take a reading from the exposed portions of the strip. In operation, as a test strip is inserted into the device, the instrument detects a change in the exposed portion and identifies the test type by reading a color coded label. A sample is then applied and the measurement cycle commences. A measurement cycle is carried out to ensure that the proper amount of sample was added to the test strip. A measurement cycle is carried out to measure the end of the reaction on the test strip. The instrument measures the density of the reaction and determines the concentration.

The method of Connolly does not entail moving a reader head over the surface of the test strip. Connolly also does not teach or suggest uniformly illuminating the surface of a test strip nor does Connolly teach or suggest

repeating the measuring and illuminating steps at a plurality of positions on the surface of the test strip nor determining an intensity or shape of an image.

Augstein

Augstein describes a measuring head for evaluating a test strip, where the measuring head rests on a spacer and thereby ensures a defined distance between the measuring head and the surface of the test strip. The test strip of Augstein has separate and different test fields separated by measuring openings, where the different test fields have different thicknesses, and the different test fields serve to evaluate different analytes. In examining various test fields, the measuring head moves relative to the test strip, where the measuring head is guided by the spacer to maintain a constant distance between the surface of each test field and the measuring head. Evaluation of each test field with different wavelengths can be carried out using several measuring heads, where each head uses one specific type of radiation.

Augstein does not teach or suggest a method that requires uniformly illuminating a test strip, nor repeating the measuring and illuminating steps at a plurality of positions on the surface of the test strip and determining a parameter associated with the intensity or shape of the image.

Analysis

It is respectfully submitted that a *prima facie* rejection of these claims has not been established because the combination of teachings of the cited references does not teach or suggest all the claim limitations to result in the instantly claimed methods. The applicability of the rejection to each independent claim is discussed in turn below.

Claim 17

a. The combination of teachings of the cited references does not result in the claimed method of claim 17

The combination of the cited references do not teach or suggest all of the claim limitations because neither Connolly nor Augstein teaches or suggests uniformly illuminating the surface of a test strip, nor taking a plurality of

readings along the surface of test strip, nor determining a parameter correlated with an intensity or shape of the image as required by claim 17. Connolly and Augstein describe the use of light sources in reflectance measurements, but do not teach or suggest any particular illumination criteria. Connolly teaches illumination of the test strip with different wavelengths positioned at different angles with respect to the test strip. (Connolly, page 21, line 30, through page 22, line 2), but does not teach or suggest uniform illumination. Augstein does not cure this deficiency. In contrast, claim 17 recites uniformly illuminating the surface of the test strip.

Claim 17 includes the further steps of moving the reader head to a second position and carrying out three additional measuring steps of the surface comprising the image. Connolly does not teach or suggest a use of a reader head. Augstein describes a measuring head that can move over a test strip in measuring separate and different test fields separated by measuring openings, where the different test fields have different thicknesses, and the different test fields serve to evaluate different analytes. (Column 1, lines 61-67). This teaching of Augstein is seen in Figure 1 and the paragraph describing Figure 1 at column 5, lines 6-23. In this figure, Augstein teaches a test strip (20) containing test fields 21a and 21b, where the test fields are physically separated and have different thicknesses. Thus, the test strip of Augstein contains a different surface for each different test field on a test strip. The movement of the measuring head permits a measurement of the surface of each test field of the test strip. (Column 4, lines 26-28). Augstein does not teach or suggest moving a reader head to a second position over the same test field and carrying out an additional measurement.

Claim 17 also recites measuring light reflected from a surface comprising an image from two different positions over the surface. Such a method permits determination of a parameter correlated with an intensity or shape of the image. Connolly does not teach or suggest measuring light reflected from a surface

from two different positions for determination of a parameter associated with an intensity or shape of an image.

Augstein does not cure this deficiency. Augstein teaches making a measurement over each of multiple different surfaces, not the same surface. As noted, Connolly does not teach or suggest carrying out measurements at a second position over the surface of the test strip. Connolly also does not teach or suggest determining a parameter correlated with an intensity or shape of the image. Accordingly, the combination of teachings of Connolly and Augstein do not result in the method of claim 17.

Because neither Connolly nor Augstein teaches or suggest uniformly illuminating the surface of the test strip nor determining a parameter correlated with an intensity or shape of the image, the references, when combined, cannot establish the method of claim 17 as *prima facie* obvious because the references do not teach or suggest all elements of the claim.

b. There would have been no motivation to do what applicant has done

The references also lack teaching or suggestion to modify or combine the references to arrive at the claimed method. As discussed above, neither Connolly nor Augstein, singly or in any combination thereof, teaches or suggests uniformly illuminating the strip. There is no teaching or suggestion within Connolly or Augstein indicating the desirability of this modification. Connolly teaches illumination at an angle with respect to the test strip. Augstein is silent with regard to the manner of illumination of the test strip. Therefore, neither Connolly nor Augstein teach or suggest desirability of illuminating the test strip uniformly. "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, at 1783-84. The cited references do not suggest the desirability of the modification. Therefore, modification of the cited references to encompass the claimed method not obvious.

Further, the teachings of Connolly or Augstein, singly or in combination, would not have led one of ordinary skill in the art to move a reader head to a second position over the surface of a test strip to take additional measurements in the manner recited in the claimed method. Connolly teaches a measurement cycle for ensuring that the proper amount of sample is applied to the test strip, a measurement cycle for determining when the end of the chemistry reaction on the test strip has occurred, and a measurement of the final density of the test strip. (Page 19, lines 5-16). If the reader head were moved to a second position over the surface and the set of three measurements taught by Connolly were carried out again, such would require applying additional sample and further chemistry reaction, resulting in a change to the image on the surface of the test strip. Alternatively, if the unchanged image on the surface of the test strip were to be measured when the reader head moved to a second position over the surface, Connolly would teach, if anything, that only a single measurement should be made. There is no suggestion by Connolly to carry out three measurements at each of two different positions for the purpose of measuring a particular image. If anything, the teachings of Connolly would motivate one skilled in the art to carry out only a single measurement after the end of the chemistry reaction on the test strip has occurred. Claim 17 recites three measurements of the surface of a test strip from a first position and three measurements of the surface of a test strip from a second position. The teachings of Connolly and Augstein do not provide motivation such that three measurements of the surface of a test strip are carried out from a first position and three measurements of the surface of a test strip are carried out from a second position. Therefore, their combination does not teach or suggest the method of claim 17.

Claims 18 and 21

Claim 18 is directed to a method for reading the surface of a test strip having an image by moving a reader head in a reflectance reader to a first

position over the surface having the image, measuring a first amount of light reflected from the surface having the image, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, and uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface. The method further includes repeating the measuring and illuminating steps at additional positions on the surface of the test strip and determining an intensity or shape of the image. Claim 21 similarly includes steps of moving the reader head to a plurality of positions and making light measurements at each of the positions to determine an intensity or shape of the image. Thus, claims 18 and 21 include measurements at further positions over the surface of the test strip and determination of an intensity or shape of an image.

For the reasons provided above regarding claim 17, claims 18 and 21, which recite measurements at further positions over the surface of the test strip, thus, are nonobvious over the cited references.

Further, claims 18 and 21 recite repeating the measuring and illumination steps to determine the intensity or shape of the image on the surface of the test strip. Neither Connolly nor Augstein teach nor suggest scanning the image on the surface of the test strip to determine its shape or intensity. Neither of the cited references provide teaching or suggestion of analysis of a scanned image. Accordingly, Connolly and Augstein, when combined, further do not teach or suggest all of the steps of the method of claim 18. Thus claims 18 and 21 further are not *prima facie* obvious over the cited references.

THE REJECTION OF CLAIMS 5-7, 11, 12, 29 AND 30 UNDER 35 U.S.C. §103(a)

Claims 5-7, 11, 12, 29 and 30 are rejected under 35 U.S.C. §103 as being unpatentable over Connolly and Augstein, and in further view of Hernicz, U.S. Patent No. 4,659,229) because Connolly, when combined with Augstein, allegedly renders the subject matter of claim 1 obvious, and Hernicz allegedly teaches a read head with an aperture and use of fiberoptic bundles to illuminate

a sample and measure reflected light. This rejection is respectfully traversed. It is noted that amendment of claim 1 to incorporate claim 2 renders the rejection moot with respect to claims 11 and 12. Claims 5-7, 29 and 30 remain rejected on this basis.

The Claims

Claim 5 is directed to a method for reading the surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface having the image, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, and uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface, where the reader contains a reader head that contains elements including a light emitting diode, a fiberoptic bundle coupled to the light emitting diode, an aperture, and fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture. As described in the application, a sigmoidal distribution is pattern of illumination selected for maximizing illumination across the lines on the test strip and which provides the uniform distribution of light emitted from the aperture and uniform distribution of light reflected back to the aperture. Claims 6, 7 and 14 are dependent on claim 5.

Claim 11 is directed to a method for reading the surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface having the image, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, and uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface. In the method of claim 11, the first wavelength is selected to reflect

equally from all regions of the test strip, where the second amount of light is indicative of a test region of the test strip.

Claim 12 is directed to the method, where light of a second wavelength reflects from a test region of the test strip, where the third amount of light is indicative of a test region of the test strip.

Claims 29 and 30 are directed to a method for reading the surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface having the image, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, and uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface. The method further includes emitting the light of the first wavelength from a light emitting diode, transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip, and transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector, where claim 30 also includes emitting the light of the second wavelength from a light emitting diode, transmitting the emitted light of the second wavelength through a third fiberoptic bundle to the surface of the test strip, and transmitting the third amount of light reflected from the surface of the test strip through a second fiberoptic bundle to the photodetector.

Teachings of the cited references

The teachings of Connolly and Augstein are discussed above. Neither Connolly nor Augstein teaches or suggests a method using fiberoptic bundles arranged in a sigmoidal distribution, which maximizes illumination across image on lines on a test strip and which provides the uniform distribution of light emitted from the aperture and uniform distribution of light reflected back to the aperture.

Hernicz

Hernicz does not cure the deficiencies in the teachings of Connolly and Augstein. Hernicz teaches a reader head with reduced height sensitivity that measures reflectance from a sample. The reader head is configured such that the upper portion of the inner surface is hemispherically shaped and the lower portion is conically shaped. In the method of Hernicz, a sample is exposed to light from a high intensity flash lamp or continuous incandescent lamp and two fiber optic bundles (one sample and one reference) receive reflected light and transfer the light to a pair of detectors.

Hernicz does not teach or suggest moving a reader over the surface of a test strip nor uniformly illuminating the test strip. Hernicz does not teach or suggest transmitting light emitted from a light emitting diode through a fiberoptic bundle to the surface of a test strip. Moreover, Hernicz does not teach or suggest transmitting light emitted from any light source through a fiberoptic bundle to the surface of a test strip nor through fiberoptic bundles arranged to achieve uniform illumination and maximize reflected light (a sigmoidal distribution).

Analysis

Claims 5-7 and 14

Claim 5, which has been rewritten as an independent claim, recites a method for reading the surface of a test strip where the reader head contains elements including fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture. As noted in the prior Office Action dated November 26, 2002 none of the cited references teaches or suggests a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture. Accordingly, the combination of teachings of Connolly, Augstein and Hernicz does not result in a method that includes a step of transmitting light emitted from a light emitting diode through a fiberoptic bundle to the surface of a test strip, where the fiberoptic conductor ends are arranged in a sigmoidal

distribution in the aperture. Claims 6, 7 and 14 depend from claim 5, and, therefore, contain all of the limitations of claim 5. Accordingly, the combination of teachings of the cited references does not result in the methods of any of claims 5-7 and 14.

Claims 29 and 30

As discussed above, Connolly and Augstein do not teach or suggest an aperture in a reader head and the use of fiberoptic bundles. Hernicz teaches use of fiberoptic bundles to receive reflected light, but does not teach or suggest transmitting light emitted from a light emitting diode through a fiberoptic bundle to the surface of a test strip. Moreover, Hernicz does not teach or suggest transmitting light emitted from any light source through a fiberoptic bundle to the surface of a test strip.

The Office Action states that the failure of Hernicz to teach a fiber optic bundle coupled to a light emitting diode is cured by the teaching in Connolly to use light emitting diodes, and, therefore, how the fiberoptic bundles are coupled would be a matter of design choice. Regardless of the light source taught in Connolly or Hernicz, neither of the cited references teaches or suggest transmitting light emitted from any light source through a fiberoptic bundle to the surface of a test strip. Accordingly, the cited references, when combined do not teach all of the elements of claims 29 and 30 because the cited references do not teach or suggest transmitting light emitted from a light source through a fiberoptic bundle to the surface of a test strip.

Furthermore, modifying the device of Hernicz to transmit emitted light through a fiberoptic bundle to the surface of the test strip would change the principle of operation of Hernicz. The reader head of Hernicz is configured such that the upper portion of the inner surface is hemispherically shaped and the lower portion is conically shaped. This the purpose of this configuration is to permit the light source to illuminate the sample surface with reduced height sensitivity. If the method of Hernicz were to be modified such that the emitted

light was transmitted by a fiberoptic bundle to the surface of the sample, the shape of the reader head would be rendered irrelevant, and, therefore, the benefits resultant from the shape of the reader head would be eliminated. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention that is modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Because the modification to Hernicz proposed by the Office Action would render the principle operation of the reader head of Hernicz useless, Hernicz cannot be combined with Connolly and Augstein to result in the methods of claim 29 or claim 30.

THE REJECTION OF CLAIMS 13 and 15 UNDER 35 U.S.C. §103(a)

Claims 13 and 15 are rejected under 35 U.S.C. §103 as being unpatentable over Connolly in view of Augstein, and further in view of Senyei (International PCT application No. WO92/10585) and May (U.S. Patent No. 4,963,324) because Connolly and Augstein allegedly teach all of the limitations of claim 1, and Senyei allegedly teaches detecting fetal fibronectin and use of a test strip with spots indicating test results, and May allegedly teaches a stripe on the surface of a test strip. This rejection is respectfully traversed. As noted, the amendment of claim 1 to incorporate claim 2 renders claim 1 and all claims dependent thereon free of the cited art. Therefore, the grounds for this rejection are obviated.

THE REJECTION OF CLAIM 14 UNDER 35 U.S.C. §103(a)

Claim 14 is rejected as being unpatentable over Connolly in view of Augstein and further in view of Hernicz and Senyei. This rejection is respectfully traversed.

Senyei

Senyei teaches methods for determining the status of a pregnancy by detecting the presence of a fetal restricted antigen such as fetal fibronectin.

Senyei does not teach or suggest uniformly illuminating the surface of a test strip.

Claim

Claim 14 is directed to the method of claim 5, where claim 5 recites a reader head containing elements including fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, where claim 14 further recites that the analyte in the sample is fetal fibronectin.

Analysis

As discussed above in regard to the rejection of claim 5, claim 14 is directed to a method for reading the surface of a test strip where the reader head contains elements including fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture. The Office Action dated November 26, 2002 has indicated that the prior art neither teach nor suggest a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture.

One element of claim 14 requires reading a surface by a reader head that includes fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture. As described in the application, a sigmoidal distribution is pattern of illumination selected for maximizing illumination across the lines on the test strip and which provides the uniform distribution of light emitted from the aperture and uniform distribution of light reflected back to the aperture. None of the references of record, singly or in any combination thereof, teaches or suggest a method that includes such an arrangement nor achieves this result.

THE REJECTION OF CLAIMS 19 AND 20 UNDER 35 U.S.C. §103(a)

Claims 19 and 20 are rejected as being unpatentable over Connolly in view of Augstein. In addition to the reasons set forth in the rejection of claims 1, 3-4, 8-9, 16-18 and 21-28, the Office Action states that the phrase "reflected normally" is not specially defined by the specification, and, further, that angular optimization is a matter of routine experimentation.
This rejection is respectfully traversed.

The Claims

Claim 19 is directed to a method for reading a surface of a test strip comprising an image, by moving a reader head in a reflectance reader to a first position over the surface comprising the image, measuring a first amount of light reflected from the surface comprising the image, transmitting light of a first wavelength onto the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface, and transmitting light of a second wavelength onto the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface.

Claim 20 is directed to a method for reading a surface of a test strip comprising an image, by, with a reader head in a reflectance reader at a first position over the surface comprising the image, measuring a first amount of light reflected from the first position of the surface comprising the image, transmitting light of a first wavelength onto the first position of the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface, transmitting light of a second wavelength onto the first position of the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface, moving the reader head to a second position over the surface comprising the image, measuring a fourth amount of light reflected from the second position on the surface comprising the image, transmitting light of the first wavelength onto the second position of the surface at an angle normal to the surface, and determining a fifth amount of light reflected normally from the surface, transmitting light of the second wavelength onto the second position of the surface at an angle normal to the surface, and determining a sixth amount of light reflected normally from the surface, and determining a parameter correlated with an intensity or shape of the image.

Analysis

As a preliminary matter, the Office Action does not acknowledge the meaning of the term "normally." In interpreting the meaning of a claim term, when a term is not defined by the Applicants in the specification, the term is to be given its plain meaning as understood by one skilled in the art. *In re Sneed*, 218 USPQ 385 (Fed. Cir. 1983). Such a meaning can be demonstrated by the use of a technical dictionary. *In re Barr* 170 USPQ 330 (CCPA 1971). The McGraw-Hill Encyclopedia of Science & Technology, 9th Edition (2002), attached herewith as Exhibit A, defines the term "normal" as "[a] term generically synonymous with perpendicular." Accordingly, the term "normally" as recited in claims 19 and 20 is generically synonymous with the term "perpendicularly."

Regarding the rejection of claims 19 and 20, neither Connolly nor Augstein teaches or suggests transmitting light onto the surface at an angle normal (or perpendicular) to the surface, and measuring light reflected normally from the surface. Furthermore, Connolly teaches the desirability of using two light sources at different angles (one at 40 degrees and one at 50 degrees) for correcting problems positioning the test strip. A tilt in the test strip will result in positive and negative contributions to the reflection readings. (Page 21, line 28, to page 22, line 8). To achieve the claimed method, one of ordinary skill in the art must orient the light at an angle normal to the surface, not at 40 or 50 degrees relative to the surface. Orienting the light at an angle normal to the surface, however, would eliminate the benefits taught by Connolly that result when the light sources are used at two different angles. Thus, to achieve the method of claims 19 or 20, one of ordinary skill in the art must proceed contrary to the teachings of Connolly.

The Office Action cites a variety of cases standing for the contention that when prior art disclose the general conditions of a claim, optimal ranges are a matter of routine experimentation. In the present case, however, Connolly

teaches more than general conditions by teaching the desirability of particular angles that are contrary to the angles of the claimed method. Moreover, modifying the angles taught by Connolly to arrive at the claimed method would eliminate the benefit taught by Connolly of having the light sources at different angles.

The totality of a reference must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986). The fact that one skilled in the art must proceed contrary to the teachings of Connolly to achieve the methods claims 19 or 20 is, therefore, evidence of the nonobviousness of claims 19 and 20. Accordingly, Applicants respectfully request that the Examiner remove this ground for rejection of claims 19 and 20.

* * *

In view of the above remarks and the amendments and remarks of record, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,
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ATTACHMENT TO THE AMENDMENT MARKED UP CLAIMS (37 C.F.R. § 1.121)

IN THE CLAIMS

Please amend claims 1, 5, 9, 11, 12, 17, 18, 20, 21, 29 and 30 as follows:

1. (Twice Amended) A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface; and

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface, wherein the reader head comprises:

a reader head body;

a light emitting diode;

a first fiberoptic bundle optically coupled to the light emitting diode;

a photodetector;

a second fiberoptic bundle optically coupled to the photodetector;

an aperture in the reader head body; and

a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, wherein: a first portion of the fiberoptic conductor ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second portion of the fiberoptic conductor ends comprises fiberoptic conductors of the second fiberoptic bundle.

5. (Amended Four Times) [The method of claim 1,] A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface; and

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface, wherein the reflectance reader comprises:

the reader head comprising:

a reader head body;

a light emitting diode;

a first fiberoptic bundle optically coupled to the light emitting diode, and adapted to transmit light from the light emitting diode;

a photodetector adapted for generating a reflection signal in response to reflected light;

a second fiberoptic bundle optically coupled to the photodetector, and adapted to transmit an amount of reflected light to the photodetector;

an aperture in the reader head body; and

a plurality of fiberoptic conductor ends arranged in a sigmoidal distribution in the aperture, wherein: a first portion of the fiberoptic conductor ends comprises fiberoptic conductors of the first fiberoptic bundle; and a second portion of the fiberoptic conductor ends comprises fiberoptic conductors of the second fiberoptic bundle, the plurality of fiberoptic conductor ends being further arranged in a substantially co-planar relationship; and a reader housing comprising:

a housing body; and

a cassette slot adapted to receive a test device.

9. (Amended Twice) The method of claim 1, wherein the method further comprises determining an amount of an analyte in a sample by correlating [the] a parameter with the amount of analyte in the sample.

11. (Amended Three Times) The method of claim 1, wherein said first wavelength is selected to reflect equally from all regions of the test strip, whereby said second amount of light is indicative of a test region of the test strip.

12. (Amended Three Times) The method of claim 1, wherein said second wavelength reflects [substantially optimally] from a test region of the test strip, whereby said third amount of light is indicative of an amount of a label at the test region.

17. (Amended) [The method of claim 1, further comprising:] A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and

moving the reader head to a second position over the surface comprising the image;

measuring a fourth amount of light reflected from the second position on the surface comprising the image;

uniformly illuminating the second position on the surface with light of the first wavelength, and measuring a fifth amount of light reflected from the surface;

uniformly illuminating the second position on the surface with light of the second wavelength, and measuring a sixth amount of light reflected from the surface; and

determining a parameter correlated with an intensity or shape of the image.

18. (Amended) [The method of claim 1, further comprising:] A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and

repeating each of the measuring and illuminating steps at additional positions on the surface until the image on the surface of the test strip is scanned; and

determining an intensity or shape of the image.

20. (Amended) A method for reading a surface of a test strip comprising an image, comprising:

with a reader head in a reflectance reader at a first position over the surface comprising the image, measuring a first amount of light reflected from the first position of the surface comprising the image;

transmitting light of a first wavelength onto the first position of the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface;

transmitting light of a second wavelength onto the first position of the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface;

moving the reader head to a second position over the surface comprising the image;

measuring a fourth amount of light reflected from the second position on the surface comprising the image;

transmitting light of the first wavelength onto the second position of the surface at an angle normal to the surface, and [determining] measuring a fifth amount of light reflected normally from the surface;

transmitting light of the second wavelength onto the second position of the surface at an angle normal to the surface, and [determining] measuring a sixth amount of light reflected normally from the surface; and

determining a parameter correlated with an intensity or shape of the image.

21. (Amended) [The method of claim 1, further comprising] A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and

moving the reader head in a stepwise fashion to a plurality of positions over the test strip, wherein three light measurements are made at each of the plurality of positions to determine an intensity or shape of the image.

29. (Amended) [The method of claim 1, further comprising] A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and

emitting the light of the first wavelength from a light emitting diode;

transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip; and

transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector.

30. (Amended) [The method of claim 1, further comprising] A method for reading a surface of a test strip comprising an image, comprising:

moving a reader head in a reflectance reader to a first position over the surface comprising the image;

measuring a first amount of light reflected from the surface comprising the image;

uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface;

uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and

emitting the light of the first wavelength from a light emitting diode;

transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip; [and]

transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector;

emitting the light of the second wavelength from a light emitting diode;

transmitting the emitted light of the second wavelength through a third fiberoptic bundle to the surface of the test strip; and

transmitting the third amount of light reflected from the surface of the test strip through a second fiberoptic bundle to the photodetector.